Message

From: Nesci, Kimberly [Nesci.Kimberly@epa.gov]
Sent: 9/13/2016 4:50:11 PM
To: Sisco, Debby [Sisco.Debby@epa.gov]; McNally, Robert [Mcnally.Robert@epa.gov]; Kausch, Jeannine [Kausch.Jeannine@epa.gov]; Overbey, Dian [Overbey.Dian@epa.gov]; Han, Kaythi [Han.Kaythi@epa.gov]; Bennett, Isabella [Bennett.Isabella@epa.gov]
CC: Dinkins, Darlene [Dinkins.Darlene@epa.gov]; Carlisle, Sharon [Carlisle.Sharon@epa.gov]; Hartman, Mark [Hartman.Mark@epa.gov]; Leahy, John [Leahy.John@epa.gov]; Strauss, Linda [Strauss.Linda@epa.gov]; Kough, John [Kough.John@epa.gov]; Carlisle, Sharon [Carlisle.Sharon@epa.gov]
Subject: RE: Wolbachia edits and proposed Q's and A's

The infected female mosquito can't infect people with Wolbachia; it's sexually transmitted between the mosquitoes. So, Wolbachia is not harmful to people. (Confirmed with John Kough.)

From: Sisco, Debby
Sent: Tuesday, September 13, 2016 12:06 PM
To: McNally, Robert <Mcnally.Robert@epa.gov>; Kausch, Jeannine <Kausch.Jeannine@epa.gov>; Overbey, Dian <Overbey.Dian@epa.gov>; Han, Kaythi <Han.Kaythi@epa.gov>; Bennett, Isabella <Bennett.Isabella@epa.gov>
Cc: Dinkins, Darlene <Dinkins.Darlene@epa.gov>; Carlisle, Sharon <Carlisle.Sharon@epa.gov>; Nesci, Kimberly <Nesci.Kimberly@epa.gov>; Hartman, Mark <Hartman.Mark@epa.gov>; Leahy, John <Leahy.John@epa.gov>; Strauss, Linda <Strauss.Linda@epa.gov>
Subject: RE: Wolbachia edits and proposed Q's and A's

Okay, some other questions: I have added Bob's and edited a bit. Can you answer the highlighted?

4. If male mosquitos are carrying a strain of bacteria, if bitten, can people be infected with the bacteria used in the EUP?

Only female mosquitoes bite people; male mosquitoes do not bite people. They cannot infect people with the bacteria.

But, if a female gets the bacteria from the male, can she infect people? Is the bacteria harmful to people?

5. Will the public be made aware of where the infected mosquitoes will be released?

   The local government would decide on whatever notifications are appropriate for their jurisdiction, working with the researchers. EPA does not require notification to affected communities for an EUP.
   This video from the New York Times may be of interest:
   http://www.nytimes.com/video/science/100000004459613/enlisting-mosquitoes-to-fight-zika.html

6. How will progress be evaluated and monitored.

   EPA is requiring the permit holder to test and monitor for and collect certain information. For example, mosquito eggs must be collected from release sites to verify a reduction in egg hatch. Once the

experimental period concludes, all of this information will be submitted to EPA as a final report for evaluation.

7. How will the EUP take into consideration the presence of variables such as weather or other natural causes?

   Yes, EPA is requiring the permit holder to monitor and record environmental conditions (e.g., temperature and wind speed) from a local National Oceanic and Atmospheric Administration station during the experimental period. Once the experimental period concludes, this information will be reported to EPA in a final report for evaluation.

8. What is the duration of the experiment?

   The original Permit began on October 15, 2015, and it now runs through December 31, 2017. Testing, however, will not be continuously done throughout this time period. When releases are done in an area, they are done weekly for up to 6 months.

Debby Sisco
Office of Pesticide Programs (7501P)
Ethics Officer and Special Assistant to the Director
Room 12651 Potomac Yard South (office: 703 308-8121; cell: 571 317-4823)

From: McNally, Robert
Sent: Tuesday, September 13, 2016 11:29 AM
To: Kausch, Jeannine <Kausch.Jeannine@epa.gov>; Sisco, Debby <Sisco.Debby@epa.gov>; Strauss, Linda <Strauss.Linda@epa.gov>; Overbey, Dian <Overbey.Dian@epa.gov>
Cc: Han, Kaythi <Han.Kaythi@epa.gov>; Dinkins, Darlene <Dinkins.Darlene@epa.gov>; Milbourn, Cathy <Milbourn.Cathy@epa.gov>; Valentine, Julia <Valentine.Julia@epa.gov>; Carlisle, Sharon <Carlisle.Sharon@epa.gov>; Nesci, Kimberly <Nesci.Kimberly@epa.gov>; Hartman, Mark <Hartman.Mark@epa.gov>; Leahy, John <Leahy.John@epa.gov>
Subject: RE: Wolbachia edits and proposed Q's and A's

Is the answer to #4:

The local government would decide on whatever notifications are appropriate for their jurisdiction, working with the researchers. EPA does not require notification to affected communities for an EUP.

One other point, Debby: I would highlight in the statement up front that only female mosquitoes bite people, not the males carrying the Wolbachia. I think getting that into our statement, rather than an answer to a question we may never get asked is important.

Thanks

Bob

From: Kausch, Jeannine
Sent: Tuesday, September 13, 2016 10:18 AM
To: Sisco, Debby <Sisco.Debby@epa.gov>; Strauss, Linda <Strauss.Linda@epa.gov>; Overbey, Dian <Overbey.Dian@epa.gov>
Cc: Han, Kaythi <Han.Kaythi@epa.gov>; Dinkins, Darlene <Dinkins.Darlene@epa.gov>; Milbourn, Cathy <Milbourn.Cathy@epa.gov>; Valentine, Julia <Valentine.Julia@epa.gov>; Carlisle, Sharon <Carlisle.Sharon@epa.gov>; Nesci, Kimberly <Nesci.Kimberly@epa.gov>; McNally, Robert <Mcnally.Robert@epa.gov>; Hartman, Mark <Hartman.Mark@epa.gov>; Leahy, John <Leahy.John@epa.gov>
Subject: RE: Wolbachia edits and proposed Q's and A's

My responses are below in highlighted text. All of them need some work, but #4, in particular, I wasn't sure how to answer.

Jeannine

From: Sisco, Debby
Sent: Tuesday, September 13, 2016 9:11 AM
To: Strauss, Linda <Strauss.Linda@epa.gov>
Cc: Han, Kaythi <Han.Kaythi@epa.gov>; Kausch, Jeannine <Kausch.Jeannine@epa.gov>; Dinkins, Darlene <Dinkins.Darlene@epa.gov>; Milbourn, Cathy <Milbourn.Cathy@epa.gov>; Valentine, Julia <Valentine.Julia@epa.gov>
Subject: FW: Wolbachia edits and proposed Q's and A's

I have made just a few minor edits to Cathy's after consulting with the BPPD expert. I think this is good. CSB and Jeannine will work on the additional questions.

Debby Sisco
Office of Pesticide Programs (7501P)
Ethics Officer and Special Assistant to the Director
Room 12651 Potomac Yard South (office: 703 308-8121; cell: 571 317-4823)

Here's my re-write -- also added some Q's – with the help of our intern—you all have to come up with A's.

Statement

EPA will approve and expand an existing experimental use permit (EUP) to infect male mosquitos with a strain of bacteria that ~~will~~ is intended to reduce the mosquito population that carries the Zika virus. The bacteria ~~helps to~~ prevent the eggs in females from fully developing – thus eventually reducing the mosquito population—without risk to people and the environment. The male mosquitoes will be infected with the bacteria that is common in most insects, but not common in the particular type of mosquito that carries the Zika virus.

Last year, the EUP was used in Fresno, California. This year the EUP will be expanded to Fresno and Orange Counties in California and Monroe County in Florida. The ~~current~~ EUP holder is the University of Kentucky, Department of Entomology.

1. **Are these GE mosquitoes?**

No, the *Wolbachia*-infected mosquitoes being released under the EUP are **not genetically modified/engineered**. There is work to genetically engineer mosquitos (see FDA information on the Oxitec mosquito), but this is not it. In this case, male mosquitos infected with the bacterium (*Wolbachia*) are released to breed with wild female mosquitoes. The bacterium causes the resulting fertilized eggs to not hatch. While the bacterium can live inside the male mosquitoes, the mosquitoes' genes are NOT modified. The bacterium does not get passed on to other generations of mosquitoes.

Other companies are developing genetically engineered mosquitos for possible use in mosquito control programs, but it is unrelated to the Wolbachia infected mosquitoes. For more on biotech: https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/epas-regulation-biotechnology-use-pest-management.

2. **How can EPA be sure the resulting testing is done in a safe and scientifically sound manner?**

We evaluate for safety before approval the experimental use permits. For more on experimental use permits: https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-12-applying-experimental-use-permit.

Here's some additional Q's and A's:

3. If male mosquitos are carrying a strain of bacteria, if bitten, can people be infected with the bacteria used in the EUP?
   Male mosquitoes feed on flower nectar and do not bite people. They cannot infect people with the bacteria.

4. Will the public be made aware of where the infected mosquitoes will be released?
   I am not sure how to address this without making some assumptions. For the testing currently being conducted in Fresno County (CA), the Consolidated Mosquito Abatement District in Fresno County has talked with individuals in at least one of the neighborhoods where releases are taking place, e.g. http://www.nytimes.com/video/science/100000004459613/enlisting-mosquitoes-to-fight-zika.html. I would think the same applies with all of the testing areas. That is, the abatement entities that the EUP holder is working with will be talking with people before releases. Also, EPA will be announcing, in the Federal Register, the counties where testing will take place.

5. How will progress be evaluated and monitored.
   During the experimental period, EPA is requiring the EUP holder to test and monitor for and collect information on certain items. For example, mosquito eggs must be collected from release sites to verify a reduction in egg hatch. Once the experimental period concludes, all of this information will be submitted to EPA as a final report for evaluation.

6. How will the EUP take into consideration the presence of variables such as weather or other natural causes?
   EPA is requiring the EUP holder to monitor and record environmental conditions (e.g., temperature and wind speed) from a local National Oceanic and Atmospheric Administration station during the experimental period. Once the experimental period concludes, this information will be reported to EPA in a final report for evaluation.

7. What is the duration of the experiment?
   The experimental period began on October 15, 2015, and runs through December 31, 2017. Testing, however, will not be continuously done throughout this time period. When releases are done in an area, they are done weekly for up to 6 months.

Debby Sisco
Office of Pesticide Programs (7501P)
Ethics Officer and Special Assistant to the Director
Room 12651 Potomac Yard South (office: 703 308-8121; cell: 571 317-4823)

From: Milbourn, Cathy
Sent: Monday, September 12, 2016 5:25 PM
To: Valentine, Julia <Valentine.Julia@epa.gov>
Cc: Sisco, Debby <Sisco.Debby@epa.gov>; Strauss, Linda <Strauss.Linda@epa.gov>
Subject: RE: Wolbachia edits and proposed Q's and A's

Thanks Julia- I hope Linda and Debby think so!

From: Valentine, Julia
Sent: Monday, September 12, 2016 5:21 PM
To: Milbourn, Cathy <Milbourn.Cathy@epa.gov>
Cc: Sisco, Debby <Sisco.Debby@epa.gov>; Strauss, Linda <Strauss.Linda@epa.gov>
Subject: Re: Wolbachia edits and proposed Q's and A's

Cathy, these are fantastic.

Julia P. Valentine
Acting Director
Office of Media Relations
202.564.2663 desk
Sent from USEPA iPhone

On Sep 12, 2016, at 5:18 PM, Milbourn, Cathy <Milbourn.Cathy@epa.gov> wrote:

Hi Debby,

Here's my re-write -- also added some Q's – with the help of our intern—you all have to come up with A's.

Statement

EPA will approve and expand an existing experimental use permit (EUP) to infect male mosquitos with a strain of bacteria that will reduce the mosquito population that carries the Zika virus. The bacteria helps to prevents the eggs in females from fully developing – thus eventually reducing the mosquito population—without risk to people and the environment. The male mosquitoes will be infected with the bacteria that is common in most insects, but not common in the particular mosquito that carries the Zika virus.

Last year, the EUP was used in Fresno, California. This year the EUP will be expanded to Fresno and Orange Counties in California and Monroe County in Florida. The current EUP holder is the University of Kentucky, Department of Entomology.

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Other companies are developing genetically engineered mosquitos for possible use in mosquito control programs, but it is unrelated to the Wolbachia infected mosquitoes. For more on biotech: https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/epas-regulation-biotechnology-use-pest-management.

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Here's some additional Q's and A's:

3. If male mosquitos are carrying a strain of bacteria, if bitten, can people be infected with the bacteria used in the EUP?

4. Will the public be made aware of where the infected mosquitoes will be released?

5. How will progress be evaluated and monitored.

6. How will the EUP take into consideration the presence of variables such as weather or other natural causes?

7. What is the duration of the experiment?

From: Milbourn, Cathy
Sent: Monday, September 12, 2016 3:41 PM
To: Sisco, Debby <Sisco.Debby@epa.gov>
Subject: FW: Wolbachia in Share Point

Jim Jones asking for when this can go. It is a good news story - EPA looking for innovative ways to solve problems. Can you let me know?

Listserv + backpocket Q's and A's

EPA Grants Extension of Experimental Use Permit for 'Wolbachia Mosquito'

EPA has approved the amendment and extension of an existing experimental use permit (EUP) for Wolbachia pipientis-infected Aedes aegypti mosquitoes. Wolbachia are naturally occurring bacteria commonly found in most insect species, but not in the Aedes aegypti. The EUP was issued to the University of Kentucky's Department of Entomology (UKDE) in October 2015 for limited testing in Fresno County, California. The updated EUP authorizes testing only in California and Florida to evaluate the Wolbachia pipientis bacteria's effectiveness in suppressing and eliminating Aedes aegypti mosquitoes at particular sites in Fresno and Orange County in California and Monroe County in Florida.
Wolbachia pipientis are bacteria that generally do not occur in wild populations of Aedes aegypti. This strain of Wolbachia is extracted from Aedes albopictus embryos and microinjected into Aedes aegypti embryos. Male mosquitoes are separated from female mosquitoes and shipped to testing sites where they are released and mate with wild-type Aedes aegypti females that do not carry Wolbachia. After mating, the bacteria prevents the embryos from developing properly so the mosquitos cannot successfully reproduce. In February 2016, EPA published a Notice of Receipt of the university's application and took public comment. EPA concluded that the experimental work initially approved for the EUP in 2015 presented minimal risks to non-target organisms and the environment. The additional sites and extended time do not raise any new risk concerns for EPA.
As the Aedes aegypti mosquitoes are known to carry numerous diseases, including the Zika virus, it is important to note that information gathered under this EUP may lead to a new tool to help control mosquitoes that carry diseases. Documents related to this EUP, including scientific assessments, are available in Docket EPA-HQ-OPP-2015-0374 on www.regulations.gov.

EPA has issued, amended, and/or extended other experimental use permits using this same

technology in another mosquito species, Aedes polynesiensis or Aedes albopictus in 2012, 2013, and 2014. Information on those EUPs is available in docket number EPA-HQ-OPP-2012-0181 and docket number EPA-HQ-OPP-2013-0254 at www.regulations.gov.
EPA expects to issue a decision on a request to amend and extend an Experimental Use Permit for the microbial pesticide Wolbachia pipientis. The current EUP allows testing in California of the microbial pesticide to control the Aedes aegypti mosquito, the mosquito transmitting the Zika virus. If granted the mosquitoes would be released in Florida. EPA expects mixed reactions. The EUP holder is the University of Kentucky, Department of Entomology.

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